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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,106	12/21/2001	Jean-Christophe Renauld	LUD 5752 DIV JEL/NDH (101	7513

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,106	RENAULD ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,24,25 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,24,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

1b. Applicants submission filed on 12 November 2004 has been entered. Claims 1 and 29 have been amended. Claims 13-23, 26-28 and 30-37 have been previously cancelled. Thus claims 1-12, 24-25 and 29 are pending and under consideration.

1c. Receipt of Applicant's declaration under 37 C.F.R §1.132, filed by the inventors of the instant application filed on 17 August 2004, is also acknowledged.

Response to Applicants' Amendment:

2. The following previous rejections are withdrawn in light of Applicants' amendment filed on 12 November 2004:

(i) The rejection of claim 29 for not satisfying the written description provision of 35 U.S.C.§112, first paragraph is withdrawn, because the description that the claimed oligonucleotide consists of 17-100 contiguous nucleotides of SEQ ID NO:7 or 9 is sufficient to satisfy this provision of the statute.

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claims 1-12, 24-25, 29 stand rejected under 35 U.S.C. 101, for reasons of record, set forth in the office actions mailed on 03/09/04 and 09/29/03, and reiterated here, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification describes the claimed nucleic acid as encoding a novel receptor designated as "LICR-2", and Applicant indicate that it is involved in STAT activation. However, as was pointed out in the previous office action, a variety of molecules activate STATs. Therefore, the fact that the protein of the instant invention activates a STAT protein is not sufficient to establish a specific and substantial asserted utility or a well established utility, because one of ordinary skill in the art would not know which physiological process is the protein of the instant invention involved in.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3b. Claims 1-12, 24, 25 and 29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification does not define the physiological role of the LICR-2 polypeptide encoded by the claimed nucleic acid, neither does it establish a link between this protein and a disease or a physiological condition. Therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded

protein. The specification discloses only the sequence of the claimed nucleic acid and the encoded protein, and that it activates STAT proteins, however, that is insufficient to establish a specific or substantial utility for the claimed invention.

37 CFR 1.132 Declarations:

4a. Applicants present a declaration filed under 37 CFR 1.132. However, this is insufficient to establish a specific or substantial utility for the claimed invention.

Applicants submit that the LICR-2 protein of the instant invention is involved in STAT activation, and in particular it activates STAT3. Applicants submit data showing that anti-LICR-2 serum abrogates the phosphorylation of STAT3. Applicants also present data showing that anti-LICR2 sera, inhibits IL-29 activation of STAT3. Applicants data has been fully considered but is not deemed persuasive to overcome the rejection of claims 1-12, 24-25 and 29 mad e under 35 U.S.C. § 101/112.

The fact that LICR-2 protein of the instant activates STAT3 is not disputed, however, this activation does not establish the physiological relevance of said protein. STAT3 is involved in a wide variety of physiological processes and is activated by variety of signaling systems. For example, IL-6 type cytokines evoke a number of distinct responses, including induction of an acute-phase response in hepatoma cells, stimulation of proliferation of B lymphocytes, and growth arrest in monocytes, (see Levy et al. The Journal of Clinical Investigation, vol.109, No.9, May 2002, pages 1143-1148, especially page 1143). Levy et al also teach that STAT3 is activated by G-CSF-R signaling during granulopoieses, HGF activates STAT3 during the process of tubule outgrowth in epithelial cells and that IL-10 requires STAT3 activation for its anti-

inflammatory properties on macrophages. STAT3 is also implicated in cancers, (see page 1144, column 1). Thus, although STAT3 activation is an important event, this transcription factor is activated by a variety of agents such as growth factors, oncogenes and cytokines, leading to a wide spectrum of responses. Accordingly, Applicants have not disclosed what responses are evoked after the LICR-2 of the instant invention activates STAT3. Does the activation of STAT3 by LICR-2 lead to cancer development, proliferation, apoptosis or survival? Without this knowledge, the physiological relevance of the LICR-2 of the instant invention cannot be ascertained.

With respect to the data showing that LICR-2 sera inhibits IL-29 activation of STAT3, the relevance of this data is not clear. Relevant literature teaches that IL-29 is related to type I interferons and IL-10 family, and that it has antiviral activities, (Sheppard et al, Nature immunology, January 2003, Vol.4, No.1, (63-68), especially see page 67). However, the instant specification does not disclose any activity for the protein encoded by the claimed nucleic acid, aside from the fact that it activates STAT. Furthermore, the instant specification does not disclose a relationship between the protein of the instant invention and IL-29. Furthermore, if there is a relationship between the protein of the instant invention and IL-29, its relevance is not clear.

Conclusion:

5. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-

0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
05 January 2005

JANET ANDRES
PRIMARY EXAMINER